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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,237	04/17/2004	Daniel R. Burnett	35744-01110	9644

35023 7590 07/05/2007  
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EXAMINER
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WIEST, PHILIP R

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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07/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/826,237

**Applicant(s)**

BURNETT, DANIEL R.

**Examiner**

Phil Wiest

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- \*Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 12-35 is/are pending in the application.
- 4a) Of the above claim(s) 12-32 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/23/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. In the response filed 3/23/07, applicant amended claims 1 and 3-7, cancelled claims 8-11, withdrew claims 12-20, and added new claims 33 and 35
2. Newly submitted claims 21-32 and 34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly presented claims 21-32 and 34, if initially presented along with claims 1-7, would have been restricted on the basis of combination/subcombination.
3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-32 and 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 6,,264,625).

5. With respect to Claim 1, Rubenstein et al. disclose an implantable fluid management system comprising a first tube member (2, 64) having a first end 68 and a second end (at 58) and a length which defines a lumen therethrough, a pump 72 fluidly coupled to the first member, and an integrated controller 10 for controlling and actuating the pump (Column 7, Lines 51-67). See Figures 9 and 10A. The system carries a fluid from a first body cavity to a second body cavity (Column 5, Lines 42-45 and Figure

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10A). Because the system is designed for implantation inside the human body and is in constant contact with bodily fluids, it is inherent that the system, including the pump, will be made of a biocompatible material. Furthermore, a portion of the drainage system is coated with antibodies specific to particular agents present in cerebrospinal fluid (Column 9, Lines 48-53). Rubenstein et al., however, does not specifically disclose that the pump is disposed in a housing having an anti-infective coating. Because the container 52 is coated with antibodies (i.e. an anti-infective coating), Rubenstein et al. clearly anticipates the need for bacteria and other infective agents in the CSF to be neutralized prior to fluid transfer. Therefore, it would have been obvious to one skilled in the art at the time of invention to also provide a coating of antibodies on the pump housing in order to prevent the transfer of infective agents when CSF is drained.

6. With respect to Claim 2, Rubenstein et al. discloses that the controller is a valve 140 located within the pump 72 (Column 10, Lines 50-51). See Figure 10D.

7. With respect to Claims 3 and 4, Rubenstein et al. discloses a pressure sensor 30 disposed on the end of each tube member (Column 9, Lines 27-36) that is programmed to send a signal to the control unit, thereby actuating the pump (18, 72) and flow-controlling valves 24 when a predetermined pressure is experienced (Column 7, Lines 51-67).

8. With respect to Claim 7, Rubenstein et al. further discloses a second tube member (2, 66) defining a lumen therethrough. Said second tubing member (2, 66) comprises a second pressure sensing element 30 at its tip 70 (Column 9, Lines 35-36).

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Said second pressure sensing element is configured to control the pump 72 (Column 7, Lines 51-67). See Figures 7 and 9.

9. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Wong et al. (US 5,947,911). Rubenstein discloses the fluid management system of Claim 1 and the placement of sensors at the end of each catheter, said sensors communicating with the pump to control the flow of fluid through the system (see rejection above). Rubenstein, however, does not disclose that the sensors are chemical sensors that detect the presence of a chemical composition. Wong et al. (hereafter Wong) discloses a device for monitoring blood chemistry comprising blood chemistry sensor 19, an analyzer 25, a system controller 23, and a pump 13 (see Figure 1). The sensor is capable of detecting various chemical parameters including concentrations of oxygen, carbon dioxide, potassium, calcium, and sodium (Column 1, Lines 51-60). The analyzer 25 receives blood chemistry data from the sensor 19 and relays said data to the controller 23. The controller then operates the pump based on the received data. The method of controlling a medical fluid flow pump based on the presence of chemicals is therefore established in the art. It would have been obvious to one skilled in the art at the time of invention to combine the device with pump control based on sensor output of Rubenstein with the Wong's use of chemical sensors to operate an infusion pump because doing so would allow the concentration of various chemicals in the body cavities to be controlled.

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10. Claims 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Melskey et al. (US 5,575,770). Rubenstein discloses the device of Claim 1, but does not specifically disclose that the system comprises anchoring means opposing the forces generated by the pump. Melskey et al. (hereafter Melskey) discloses an implantable pumping means wherein a plurality of suture rings are distributed around the perimeter of the pump to anchor the pump to the adjacent tissue to anchor the pump (Column 4, lines 58-61). Furthermore, because the pump is meant to be implanted in the body and does not have an anti-growth coating, it is inherently made of a biocompatible material, and therefore is capable of promoting fibrotic growth into the housing. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the system of claim 1 with the pump anchoring means of Melskey in order to prevent pump vibrations from causing the system to move within the body.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW  
6/21/07

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', is written over the printed name and title.